

MAR 30 2005

NovoFine® Autocover™ 30G  
Disposable Safety Needle

510(k) Premarket Notification

Date: 17 Jan 2005  
Version: 1  
Status: Final

Novo Nordisk

Novo Nordisk Inc.

**10 807.87(h) 510(k) Summary****As required by Section 807.92(a)****(1) DATE OF PREPARATION: January 15, 2005**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. NovoFine® Autocover™ 30 G x 8 mm needles meet all applicable product and quality standards for hypodermic single lumen needle products.

**SUBMITTER'S NAME AND ADDRESS:**

Novo Nordisk Inc.  
100 College Road West  
Princeton, New Jersey 08540

Contact Person: John Signorin  
Tel: 609-987-5967  
Fax: 609-987-3916

**(2) NAME OF DEVICE:**

Proprietary Name:	NovoFine® Autocover™ 30G x 8 mm needles
Common or usual name:	Sterile disposable hypodermic needle
Classification:	Hypodermic single lumen needle
Class:	Class II

**(3) SUBSTANTIAL EQUIVALENCE:**

The NovoFine® Autocover™ 30G x 8 mm needle is substantially equivalent to the Novo Nordisk NovoFine® 31G x 6 mm needle (K002403) which was cleared by FDA in December 2000 and the Becton Dickinson BD SafetyGlide™ 25G x 16mm needle (K951254) which was cleared by FDA in October 1995.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the

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#### **807.87(h) 510(k) Summary (continued)**

resolution of patent infringement suits or any other patent matters. No statement related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent laws or their application by the court.

#### **(4) DEVICE DESCRIPTION:**

The NovoFine® Autocover™ 30G x 8mm needle is designed for single use in conjunction with insulin injection delivery devices. Prior to giving an injection, the protective tab is removed from the plastic needle cap of the single-use disposable needle. With the disposable needle remaining in the needle cap, it is then carefully screwed onto the delivery injection device until tight and then the needle cap is removed. Prepare for injection by following the procedure described in the instruction leaflet provided with the pen injection device and instructions from your health care professional. While pushing the needle into the skin, the shield and lock will be pushed into the house enabling the needle to penetrate the skin barrier and into the subcutaneous tissue.

After the injection, the needle is removed from the skin. The NovoFine® Autocover™ needle stick safety mechanism will activate automatically when the needle is withdrawn from the skin. Once NovoFine® Autocover™ is in the locked position, it can no longer be used. The needle is not exposed protecting against an unintentional needlestick. The red indicator windows tells the user that the safety lock has been activated. The needle is detached from the injection device and disposed of in accordance with local regulations. For each subsequent injection, another disposable needle must be used. Delivery device function checks can be performed with the NovoFine Autocover by using the needle cap as described in the instruction leaflet

#### **(5) INTENDED USE:**

The intended use for the modified device remains the same as the predicate devices (NovoFine® 31G x 6 mm and BD Safety Glide 25G x 16 mm):

For use in conjunction with insulin injection delivery devices for subcutaneous administration of sterile parenteral insulin products.

Additionally, after withdrawal of the needle from the body, the attached needle safety shield will automatically cover the needle to minimize the risk of accidental needlestick.

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**807.87(h) 510(k) Summary (continued)**

**(6) TECHNOLOGICAL CHARACTERISTICS:**

The NovoFine® Autocover™ 30G needle is substantially equivalent to the NovoFine® 31G and BD SafetyGlide 25G needle in intended use, technology/principle of operation, materials and performance. Differences between the devices do not raise any significant issues of safety and effectiveness.

**Section 807.92(b)**

**(1) NON-CLINICAL TESTS PERFORMED:**

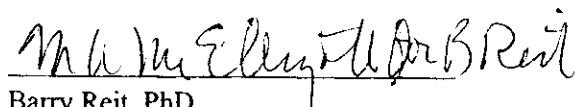
The NovoFine® Autocover™ 30G needles will be manufactured in accordance with current Good Manufacturing Practices for Medical Devices. Biocompatibility and performance tests have been performed and the results are in compliance with existing domestic and international standards.

**(2) CLINICAL TESTS SUBMITTED:**

Handling tests were conducted to investigate the efficacy and safety of the NovoFine® Autocover™ 30G disposable safety needles by diabetes nurse educators, diabetes patients and staff nurses. Differences between the devices tested do not raise any significant issues of safety and effectiveness.

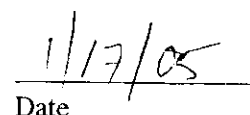
**(3) CONCLUSIONS DRAWN FROM THE NON-CLINICAL AND CLINICAL TESTS:**

Based on the design equivalency and the functional and safety testing, Novo Nordisk had determined that the NovoFine® Autocover™ 30G x 8 mm needles are substantially equivalent to the devices currently marketed in the United States. Differences between the devices do not raise any significant issues of safety and effectiveness.



Barry Reit, PhD

Vice President, Regulatory Affairs & Quality Assurance  
Novo Nordisk Inc.

  
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 30 2005

Mr. John Signorin  
Manager, Regulatory Affairs  
Novo Nordisk, Incorporated  
100 College Road West  
Princeton, New Jersey 08540

Re: K050106  
Trade/Device Name: NovoFine® Autocover™ 30G x 8 mm Disposable Safety Needle  
Regulation Number: 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Regulatory Class: II  
Product Code: FMI  
Dated: January 17, 2005  
Received: January 18, 2005

Dear Mr. Signorin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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## 2 Indication for Use Statement

510(k) Number (if known)

Not available K050106

Device Name:

NovoFine® Autocover™ 30G x 8 mm  
Disposable Safety Needle

Indications For Use:

NovoFine® Autocover™ 30G x 8 mm needles are used in conjunction with insulin injection delivery devices for subcutaneous administration of sterile parenteral insulin products.

Additionally, after withdrawal of the needle from the body, the attached needle safety shield will automatically cover the needle to minimize the risk of accidental needlestick.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

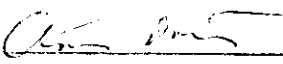
AND/OR

Over-The-Counter Use ✓  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number K050106